



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2018-0036; FRL-9980-20]

1,1-Difluoroethane; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation amends an exemption from the requirement of a tolerance to allow for residues of 1,1-difluoroethane (CAS Reg. No. 75-37-6) when used as an inert ingredient (aerosol propellant) in bird repellent pesticide products applied to growing crops and raw agricultural commodities after harvest and to animals. Pyxis Regulatory Consulting, on behalf of Avian Enterprises Limited LLC, submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an amendment to an existing requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of 1,1-difluoroethane when used in accordance with the terms of the exemption.

DATES: This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days*

*after date of publication in the **Federal Register**], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).*

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2018-0036, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Michael L. Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: RDFRNotices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2018-0036 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of*

*publication in the **Federal Register***]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2018-0036, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Petition for Exemption

In the **Federal Register** of March 21, 2018 (82 FR 12311) (FRL-9974-76), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (IN-11082) by Pyxis Regulatory Consulting (4110 136TH ST CT NW, Gig Harbor, WA 98332) on behalf of Avian Enterprises Limited LLC (2000 Pontiac Drive, Sylvan Lake, MI 48320). The petition requested that 40 CFR 180.910 and 40 CFR 180.930 be amended by modifying the current exemptions from the requirement of a tolerance for residues of 1,1-difluoroethane (CAS Reg. No. 75-37-6) when used as an inert ingredient (propellant) in pesticide formulations applied to growing crops and to raw agricultural commodities after harvest and to animals to allow for the additional use in bird repellent pesticide formulations applied to growing crops, raw agricultural commodities after harvest, and animals. That document referenced a summary of the petition prepared by Pyxis Regulatory Consulting on behalf of Avian Enterprises Limited LLC, the petitioner, which is available in the docket, <http://www.regulations.gov>. No relevant comments were received on the notice of filing.

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term “inert” is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has

exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

IV. Aggregate Risk Assessment and Determination of Safety

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Consistent with FFDCA section 408(c)(2)(A), and the factors specified in FFDCA section 408(c)(2)(B), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for 1,1-difluoroethane including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with 1,1-difluoroethane follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the adverse effects caused by 1,1-difluoroethane as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in this unit.

In an acute inhalation toxicity study in rats for 1,1-difluoroethane, the lethal concentration, LC_{50} is $> 475,500$ parts per million (ppm) (oral equivalent approximately 235,399 milligram/kilogram/day (mg/kg/day)).

No adverse toxic effects are observed in rats treated via inhalation with 1,1-difluoroethane following subchronic exposure up to 100,000 ppm (oral equivalent approximately 82,600 mg/kg/day), chronic exposure up to 25,000 ppm (oral equivalent approximately 20,649 mg/kg/day) or developmental toxicity studies at doses up to 50,000 ppm (oral equivalent approximately 41,300 mg/kg/day), the highest dose tested in each exposure scenario.

Although reproduction toxicity studies are not available with 1,1-difluoroethane, EPA does not expect 1,1-difluoroethane to cause any reproductive toxicity effects. Fetal susceptibility was not observed in the developmental toxicity study via inhalation with rats treated with 1,1-difluoroethane as neither maternal nor developmental toxicity is observed up to 50,000 ppm (oral equivalent approximately 41,300 mg/kg/day), the highest dose tested. Additionally, no signs of systemic toxicity or reproduction organ toxicity are observed following subchronic and chronic exposures at 100,000 ppm (oral equivalent approximately 82,600 mg/kg/day) and 25,000 ppm (oral equivalent approximately 20,649 mg/kg/day), the highest doses tested, respectively.

Toxicity is not observed in the carcinogenicity/chronic toxicity study via inhalation with rats treated with 1,1-difluoroethane up to 25,000 ppm (oral equivalent approximately 20,649 mg/kg/day), the highest dose tested. Therefore, 1,1-difluoroethane is not expected to be carcinogenic.

Mutagenicity studies are available with 1,1-difluoroethane. The bacterial reverse mutation test and the micronucleus test were negative. The mammalian chromosomal aberration test in human lymphocytes gave a weak positive response and the sex-linked

recessive lethal test in *Drosophila melanogaster* gave a positive response. Based on the submitted studies the mutagenic potential of 1,1-difluoroethane is equivocal.

Neurotoxicity and immunotoxicity studies are not available for review. However, evidence of neurotoxicity and immunotoxicity is not observed in the submitted studies.

The metabolism study was conducted with difluoromethane which is structurally similar to 1,1-difluoroethane. Difluoromethane differs only by a carbon atom and is considered a suitable surrogate chemical as it would be expected to be metabolized in a fashion similar to 1,1-difluoroethane. Therefore, data from the metabolism study conducted with difluoromethane are used to describe 1,1-difluoroethane metabolism. Based on the metabolism study in rats treated with difluoromethane, 1,1-difluoroethane is expected to be poorly absorbed and rapidly metabolized. Of the absorbed dose, most is expected to be metabolized and excreted via exhaled carbon dioxide and organics followed by excretion in the urine and feces.

B. Toxicological Points of Departure/Levels of Concern

The available toxicity studies indicate that 1,1-difluoroethane has a very low overall toxicity. The lowest NOAEL in the database was 25,000 ppm (approximately 20,649 mg/kg/day human equivalent oral dose) observed in a chronic/carcinogenicity toxicity study in rats via the inhalation route of exposure. Since signs of toxicity were not observed at levels well above the limit dose (1,000 mg/kg/day) an endpoint of concern for risk assessment purposes was not identified. Therefore, since no endpoint of concern was identified for the acute and chronic dietary exposure assessment as well as

for short- and intermediate-term dermal and inhalation exposure, a qualitative risk assessment for 1,1-difluoroethane was conducted.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to 1,1-difluoroethane, EPA considered exposure under the proposed exemptions from the requirement of a tolerance, as well as the existing exemptions and from other dietary sources of exposure. EPA assessed dietary exposures from 1,1-difluoroethane in food as follows:

Dietary exposure (food) to 1,1-difluoroethane can occur following ingestion of foods with residues from treated crops or animals or from the use of 1,1-difluoroethane as an aerosol propellant in consumer products used in or on food. However, a dietary exposure assessment was not conducted since no endpoint of concern was identified in the available database.

2. *Dietary exposure from drinking water.* Since a hazard endpoint of concern was not identified for the acute and chronic dietary assessment, a quantitative dietary exposure risk assessment for drinking water was not conducted, although exposures may be expected from use on food crops and runoff in the ground water.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., textiles (clothing and diapers), carpets, swimming pools, and hard surface disinfection on walls, floors, tables).

1,1-Difluoroethane may be used in pesticide products and non-pesticide products that may be used in and around the home. Based on the discussion above, a quantitative residential exposure assessment for 1,1-difluoroethane was not conducted.

4. *Cumulative effects from substances with a common mechanism of toxicity.*

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.”

Based on the available data, 1,1-difluoroethane does not have a toxic mechanism; therefore, section 408(b)(2)(D)(v) does not apply.

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act Safety Factor (FQPA SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

As part of its qualitative assessment, the Agency did not use safety factors for assessing risk, and no additional safety factor is needed for assessing risk to infants and

children. Based on an assessment of 1,1-difluoroethane, EPA has concluded that there are no toxicological endpoints of concern for the U.S. population, including infants and children.

E. Aggregate Risks and Determination of Safety

Because no toxicological endpoints of concern were identified, EPA concludes that the exemptions from the requirement of a tolerance to residues of 1,1-difluoroethane are safe, i.e., there is a reasonable certainty that no harm will result to the general population, or to infants and children, from aggregate exposure to 1,1-difluoroethane residues.

V. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

VI. Conclusions

Therefore, the exemptions from the requirement of a tolerance for residues of 1,1-difluoroethane (CAS Reg. No. 75-37-6) contained in 40 CFR 180.910 and 180.930 are amended to add the use of 1,1-difluoroethane in bird repellent pesticide formulations.

VII. Statutory and Executive Order Reviews

This action amends exemptions from the requirement of a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under

Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997), nor is it considered a regulatory action subject to Executive Order 13771, entitled “Reducing Regulations and Controlling Regulatory Costs” (82 FR 9339, February 3, 2017). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are amended on the basis of a petition under FFDCA section 408(d), such as the tolerance exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the

distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VIII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: July 11, 2018.

Michael L. Goodis,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In §180.910, revise the inert ingredient “1,1-Difluoroethane (CAS Reg. No. 75-37-6)” in the table to read as follows:

§ 180.910 Inert ingredients used pre- and post-harvest; exemptions from the requirement of a tolerance.

Inert ingredients	Limits	Uses
**	***	**
1,1-Difluoroethane (CAS Reg. No. 75-37-6)	In pesticide formulations used for insect control in food- and feed-handling establishments and animals; in bird repellent pesticide formulations.	Aerosol propellant
**	***	**

3. In §180.930, revise the inert ingredient 1,1-Difluoroethane (CAS Reg. No. 75-37-6) in the table to read as follows:

§ 180.930 Inert ingredients applied to animals; exemptions from the requirement of a tolerance.

Inert ingredients	Limits	Uses
**	***	**
1,1-Difluoroethane (CAS Reg. No. 75-37-6)	In pesticide formulations used for insect control in food- and feed-handling establishments and animals; in bird repellent pesticide formulations.	Aerosol propellant
**	***	**

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